STATE OF MICHIGAN
IN THE SUPREME COURT

ANTONIO CRAIG, minor, by his Next Friend and Mother, KIMBERLY CRAIG,

Plaintiff-Appellee,

and

KIMBERLY CRAIG, Individually,

Plaintiff, Not Participating,

v.

OAKWOOD HOSPITAL, a Michigan Corporation,

Defendant-Appellant,

and

AJIT KITTUR, M.D., DR. GAVINI, DR. LAKE, MARGARETT LAWRENCE, R.N., J. TYRA, R.N., K. KONIETZKO, R.N., R. HILL, R.N., KAREN SOWISLO, DIRECTOR OF MEDICAL RECORDS, CHILDREN'S HOSPITAL, DR. R. ASMAR, DR. CASH, DR. HERMAN GRAY, DR. H. WALKER, DR. MARY LOGAN, DR. CAROLYN JOHNSON,

Defendants, Not Participating,

and

ASSOCIATED PHYSICIANS, P.C. and ELIAS G. GENNAOUI, M.D., and HENRY FORD HOSPITAL d/b/a HENRY FORD HEALTH SYSTEM

Defendants.

SUPREME COURT NO. 121419

COURT OF APPEALS NO. 206951

Wayne County Circuit Court
No. 94-410338-NH

BRIEF OF AMICUS CURIAE THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS ("ACOG")

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BRIEF OF AMICUS CURIAE
THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

PROOF OF SERVICE

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STATEMENT OF QUESTIONS PRESENTED FOR REVIEW AND ADDRESSED BY ACOG'S *AMICUS CURIAE* BRIEF

I. **Did the trial court and Court of Appeals commit reversible error by refusing Defendants' timely request for a Davis-Frye hearing on the admissibility of expert testimony by plaintiffs' expert witnesses?**

ACOG answers: Yes

This Court should answer: Yes

II. **Did the trial court and Court of Appeals commit reversible error in holding that the Defendants, as the objecting parties, had the burden to present evidence that the theories of the plaintiff's, or proferring party's, expert witnesses lacked factual and scientific support to obtain a Davis-Frye hearing?**

ACOG answers: Yes

This Court should answer: Yes

III. **Did the Court of Appeals commit reversible error in holding that the trial court need not conduct a Davis-Frye hearing to determine the admissibility of expert testimony unless the objecting party presents evidence that the proferred theory is "novel?"**

ACOG answers: Yes

This Court should answer: Yes

IV. **Did the trial court and Court of Appeals commit reversible error by permitting the plaintiffs' expert witnesses to testify to theories that lack factual and/or scientific support?**

ACOG answers: Yes

This Court should answer: Yes

V. **Did the trial court and Court of Appeals commit reversible error by permitting plaintiffs' counsel, over Defendants' objections, to improperly and falsely state to the jury in closing argument that the drug "Pitocin is not on the market any more" and infer that it had been withdrawn or was not approved by the FDA?**

ACOG answers: Yes

This Court should answer: Yes

ORDERS APPEALED AND RELIEF SOUGHT

Following a trial of this case in 1997, the trial court entered judgment in favor of the plaintiffs against defendants Dr. Elias Gennaoui, an obstetrician-gynecologist, and Oakwood Hospital. The trial court subsequently entered an order denying all post-trial motions filed by the defendants. On February 1, 2002, the Michigan Court of Appeals affirmed the judgment of the trial court on all matters pertinent to this brief.[1] The American College of Obstetricians and Gynecologists submits this brief as amicus curiae requesting reversal of the judgments of the Court of Appeals and the trial court because of fundamental errors that allowed scientifically unreliable testimony and inaccurate argument to be presented to the jury that decided this case.

STANDARD FOR REVIEW

Although issues regarding the admissibility of evidence are ordinarily reviewed on an abuse of discretion standard, *People v. Layher,* 464 Mich 756, 761, 631 NW2d 281 (2001), this case involves issues of the role and responsibility of the trial court in ensuring the reliability of proposed expert testimony, the manner in which the court is to make a determination of whether proferred expert testimony is "recognized" as required by Michigan's Rules of Evidence, and preliminary legal questions of whether the rules of evidence preclude admission of proffered testimony. These are questions of law, which are reviewed *de novo. Id.; Kelly v. Builders Square,* 465 Mich 29, 34; 632 NW2d 912 (2001).

STATEMENT OF MATERIAL PROCEEDINGS AND FACTS

The material facts of the case have been exhaustively briefed by the parties and so will not be restated here. The following facts material to the position of this amicus curiae do not appear to be in dispute:

[1] *Craig v. Oakwood Hospital,* 249 MichApp 534, 643 NW2d 580 (2002).

1. Plaintiffs presented expert testimony at trial from Dr. Ronald Gabriel. Defendants challenged the scientific basis for Dr. Gabriel's theories and opinions in a pre-trial motion and requested the trial court to conduct a *Davis-Frye* hearing to determine the admissibility of his opinions under MRE 702.

2. The trial court refused the request for a *Davis-Frye* hearing because the defendants did not produce any affidavits or evidence, other than the expert's deposition, that showed the need for a *Davis-Frye* hearing.

3. The Court of Appeals held that the trial court had no obligation to conduct a *Davis-Frye* hearing because the defendants had not presented any evidence that the expert's theories were "novel." *Craig v. Oakwood Hospital,* 249 Mich.App. 534, 546, 643 N.W.2d 580, 585 (2002).

4. Dr. Gabriel was permitted to testify at trial to the following theory of brain injury:

> I think the injury occurred in two ways. First there was a compression of the head through grinding experience with the head in the pelvic rim, accentuated by the high uterine pressures from Pitocin producing decelerations which were quite marked after a certain point in time.
>
> And this resulted in compression, producing a compression injury over the surface of the brain. And this in turn also resulted in elevation in ven[o]us pressures of the brain which then impedes arterial blood flow. (TR XIII, pp. 18-19).[2]

Dr. Gabriel also testified that the injury had a "traumatic component as well as a vascular component" with the "head being pounded or grinded into the pelvic rim with successive uterine contractions which were of high pressure and which resulted in marked decelerations." (TR XIII, p.39).[3]

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[2] Cited in Defendant-Appellant Oakwood Hospital's Application for Leave to Appeal, p. 18.

[3] Cited in Plaintiff-Appellee's Consolidated Brief, pp. 36-37.

5. Counsel for Plaintiffs told the jury in closing argument, over defendants' objection that the argument was not supported by the evidence, that "Pitocin is not on the market any more. Oxytocin is, not Pitocin." (TR XXVI, p.27).

ARGUMENT AND AUTHORITIES

I. Introduction

The American College of Obstetricians and Gynecologists ("ACOG") is a nonprofit national medical organization of obstetrician-gynecologists founded in 1951. Its more than 45,000 physicians, including more than 1,500 in Michigan, specialize in providing health care for women and include approximately 93% of all board-certified obstetricians and gynecologists practicing in the United States. The issues presented in this case are of great importance to ACOG because the standards for professional conduct that are established on a case-by-case basis in the courtroom can have an immediate and lasting impact on its members' medical practices, the price and availability of professional liability insurance, and the price and availability of medical products and services.

This case involves an appeal from a multi-million dollar verdict against an obstetrician-gynecologist and a hospital in a medical malpractice case. Plaintiffs allege that Antonio Craig was injured as a result of the medical care given to his mother during labor and delivery. ACOG submits this brief as amicus curiae because of serious concern that the trial court (1) refused to fulfill its assigned role of ensuring that expert testimony was reliable, (2) improperly placed the burden on the party challenging expert testimony to demonstrate that it is not generally scientifically recognized, (3) allowed unreliable and scientifically unsupported expert opinions to be admitted into evidence, and (4) permitted the jury to hear untrue argument about a drug in

widespread use by obstetricians throughout the United States. ACOG has similar concern over the action of the Court of Appeals in upholding these decisions of the trial court, which are contrary to precedents of this Court and the U.S. Supreme Court, and over the holding of the Court of Appeals that the trial court need not conduct a hearing to evaluate the scientific reliability of an expert's opinion without a showing by the challenging party that the opinion or theory is "novel."

II. The Requirement of a *Davis-Frye*/MRE 702 Hearing

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 US 579, 113 SCt 2786, 125 LEd2d 469 (1993), the U.S. Supreme Court affirmed the responsibility of trial judges to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." 509 US at 589, 113 SCt at 2795. The Court ruled that a trial judge, when faced with a proffer of scientific testimony, must "determine at the outset" whether "the reasoning or methodology underlying the testimony is scientifically valid." 509 US at 592, 113 SCt at 2796. The high court later concluded that this "gatekeeping" function of the trial judge applies to all expert testimony. *Kumho Tire Co., Ltd. v. Carmichael,* 526 US 137, 147, 119 SCt 1167, 1174, 143 LEd2d 238 (1999).

Interpreting Rule 702 of the Federal Rules of Evidence,[4] the Court noted a number of factors for trial courts to consider in making this required preliminary assessment:

1) whether the theory or technique can be, and has been, tested;

2) whether the theory or technique has been subjected to peer review and publication;

[4] "If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise."

3) with respect to a particular technique, its known or potential rate of error;

4) the existence and maintenance of standards controlling the technique's operation; and

5) the "general acceptance" of the theory or technique in a relevant scientific community.

The *Daubert* holdings, including the trial court's required gatekeeping function and the factors to be considered, have since been adopted by statute in Michigan. MCL §600.2955.

Michigan's own evidentiary rule governing expert testimony, MRE 702, is similar to the federal rule with the important addition of five words: "the court determines that" and "recognized."[5] The rule thus specifically requires a determination by the trial judge of its application, and that the scientific, technical or other specialized knowledge which is the subject of expert testimony be "recognized." The courts of Michigan have long utilized the so-called *Davis-Frye* test of "general scientific recognition" or "general scientific acceptance" to determine the admissibility of expert theories and opinions. *Frye v. United States,* 54 USAppDC 46, 293 F 1013 (1923); *People v. Davis,* 343 Mich 348, 72 NW2d 269 (1955). "General scientific recognition" has been interpreted to mean acceptance for reliability among impartial and disinterested experts, *People v. Young,* 418 Mich 1, 21, 340 NW2d 805, 813 (1983), and containing inferences or assertions resting in "application of scientific methods" and "supported by appropriate objective and independent validation based on what is known, e.g. scientific and medical literature." *Nelson v. American Sterilizer Co.,* 223 MichApp 485, 566 NW2d 671 (1997). In *People v. Young, supra*, this Court specifically held that the *Davis-Frye* standard is the means for determining whether offered expert testimony enjoys the recognition required by MRE 702. 418 Mich at 24.

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[5] If *the court determines that recognized* scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise."

While many might argue that the *Davis-Frye* analysis should be replaced by the *Daubert* form of inquiry, the trial court erred in this case under either standard because **it made no inquiry or determination at all**. The defendants objected before trial to the proposed testimony of plaintiffs' expert, Dr. Ronald Gabriel, on the grounds that it was not scientifically reliable and not supported by the medical literature. The trial court refused the defendants' request for a *Davis-Frye* hearing, did not make a determination that the expert's theories or opinions enjoyed general scientific acceptance or recognition, did not require the offering party to demonstrate the general scientific acceptance for the expert's theories among impartial and disinterested experts, and simply permitted the expert to testify to his opinions before the jury. The trial court thus wholly failed to make the determinations mandated by MRE 702 and MRE 104(a), *Davis-Frye, Daubert,* MCL §600.2955, or any other applicable authority.

The trial court's role as gatekeeper is the same under all of these standards:

1. *Davis-Frye*: "The *Davis-Frye* standard is the means by which the court can determine that the novel evidence offered here for admission enjoys such recognition . . . a *Davis-Frye* hearing should have been held." *People v. Young,* 418 Mich at 24.

2. MRE 702: "Under the rules of evidence, the trial court was charged with ensuring that any and all scientific testimony to be admitted was not only relevant, but also reliable." *Nelson,* 212 MichApp at 589.

3. *Daubert:* "[T]he trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." 509 US at 589, 113 SCt at 2795. "[W]here such testimony's factual basis, data, principles, methods or their application are sufficiently called into question...the trial judge must determine whether the testimony has 'a reliable basis in the knowledge and experience of [the relevant] disicipline." *Kumho Tire,* 526 US at 149, 119 SCt at 1175, citing *Daubert.*

4. MCL §600.2955: "[A] scientific opinion rendered by an otherwise qualified expert is not admissible unless the court determines that the opinion is reliable and will assist the trier of fact."

It is also clear that the trial judge must fulfill this role as gatekeeper and make its determination of reliability **before** the expert testimony is admitted into evidence. *People v. Young,* 418 Mich at 21; *Tobin v. Providence Hospital,* 244 MichApp 626, 651, 624 NW2d 548, 560 (2001).

The trial court based its refusal to conduct a *Davis-Frye* hearing on the defendants' failure to offer evidence of the need for a hearing other than Dr. Gabriel's own deposition. ACOG respectfully submits that the objection alone should ordinarily be sufficient to trigger the mandated determination by the court. As the burden of demonstrating that the proposed expert testimony is reliable clearly rests with the offering party, *Young, supra,* the objecting party should not be required, as it was here, to offer evidence of non-reliability before the trial court conducts its inquiry. In *People v. Davis,* this Court appears to have required no more than an objection by the party opposing admission of lie detector results to trigger the need for evidence of general scientific recognition from the proffering party. 343 Mich at 369. This approach is also followed in other jurisdictions. *See, e.g., E.I. du Pont de Nemours and Company, Inc. v. Robinson*, 923 SW2d 549, 557 (Tex. 1995).

Should some preliminary showing of suspicion of unreliability be required by this Court to trigger a trial court's duty to conduct a *Davis-Frye* hearing, ACOG submits that a sufficient showing was made in this case. Defendants offered Dr. Gabriel's own deposition testimony that:

- he could not cite any references to any literature supporting his opinions other than a vague reference to "references on the subject after World War II" (p. 100),
- this phenomenon "is not discussed any more in modern literature" (pp. 100-101),
- "it's so rare as to no longer be a subject of the medical literature" (p. 101).

Whether a theory has been subjected to peer review and publication is one of the key factors listed by the Supreme Court in *Daubert* and adopted by the Michigan legislature in MCL

§600.2955.[6] The Michigan Court of Appeals has also recognized the importance of support in the literature in determining a theory's reliability and recognition. *Nelson,* 223 MichApp at 491 ("the inferences or assertions must be supported by appropriate objective and independent validation based on what is known, e.g. scientific and medical literature"). The expert's own deposition testimony, at a minimum, raised a question of whether there was **any** scientific or medical literature to support his theory of compression injury. One must certainly view with skepticism testimony by a supposed expert in the field that his theory is so rare that it is not found in textbooks or literature. It may well be so rare and unpublished because it is not deemed reliable by the scientific and medical community.

These problems with the expert's own testimony should have caused the trial court to conduct a *Davis-Frye*/MRE 702 hearing. *Tobin,* 244 MichApp at 650. The objecting party should not bear the burden of providing evidence on every conceivable factor that a court might consider in determining reliability, for the burden rests on the offering party to demonstrate the required degree of scientific acceptance. By failing to conduct a Rule 702/*Davis-Frye* hearing before admitting Dr. Gabriel's testimony, the trial court violated the mandates of this Court and the Court of Appeals that "the reliability of the expert's testimony is to be determined by the *judge* in advance of its admission – not by the jury at the conclusion of the trial by evaluating the testimony of competing expert witnesses." *Id.* at 651.

III. The Burden of Demonstrating Reliability

By holding that the objecting party (defendants) had not presented any evidence that Dr. Gabriel's theories were not generally accepted, the trial court improperly shifted the burden of proof on the issue of reliability to the objecting party. By holding that the objecting party had

[6] MCL 600.2955(1)(b).

the duty to present evidence to demonstrate the novelty of the expert's opinion before the trial court had a duty to conduct a *Davis-Frye* hearing, the Court of Appeals likewise shifted the burden to the objecting party. ACOG respectfully submits that both of these rulings are contrary to long-established precedent that properly places the burden of demonstrating the reliability of expert testimony on the offering party.

Michigan courts have long held that the party *offering* scientific evidence bears the burden of demonstrating its general scientific acceptance and reliability before the evidence is admissible. *People v. Young,* 418 Mich. at 21; *People v. Barbara,* 400 Mich 352, 365, 255 NW2d 171, 175 (1977). The same rule applies in the federal courts. *See, e.g. Moore v. Ashland Chemical, Inc.,* 151 F3d 269, 276 (5th Cir. 1998) (*en banc*), *In re Paoli R.R. Yard PCB Litigation,* 35 F3d 717, 743-744 (3rd Cir. 1994). In this case, both the trial court and Court of Appeals erred in requiring the objecting parties to produce evidence of the unreliability or novelty of the expert's opinions. Once the objection had been made that the testimony was unreliable (especially coupled with the preliminary showing of suspicion for unreliability based on the expert's own deposition testimony), ACOG submits that the courts should have followed Michigan law and required the proponent of the testimony to present evidence to demonstrate its reliability. The burden of proof was incorrectly placed in this case.

IV. The Requirement of Novelty

The Court of Appeals incorrectly held that the trial court need not conduct a *Davis-Frye* hearing unless the proferred expert testimony or theory is "novel." 238 MichApp at 678. While novelty of a theory or opinion may well be one factor that compels a trial judge to fulfill its role of "gatekeeper" and subject the theory to close scrutiny, it is not and cannot be the only factor, or

even the controlling factor, that triggers such an inquiry. ACOG respectfully submits that the Court of Appeals has misinterpreted the previous rulings of this Court and that novelty of a theory is not the only basis for conducting a *Davis-Frye* hearing.

In *People v. Young,* this Court was called on to consider "identification evidence obtained by blood analyses using the *novel* technique of serological electrophoresis." 418 Mich at 17 (emphasis added). Because the Court in that particular case was indeed addressing a novel scientific theory, Justice Brickley used that terminology several times in his opinion:

> "...despite our invariant and unanimous application of the *Davis-Frye* rule to the admissibility of *novel scientific evidence...,*"[7]
>
> "...the party offering *novel scientific evidence* has the burden of demonstrating general scientific acceptance for reliability...,"[8]
>
> "The *Davis-Frye* standard is the means by which the court can determine that the *novel evidence* offered for admission here enjoys such recognition."[9]
>
> "We hold that the admissibility of *novel scientific evidence* is governed by the *Davis-Frye* standard."[10]

The Court of Appeals in this case, in ultimate reliance on this language,[11] held that a *Davis-Frye* inquiry was unnecessary because the defendants failed to present evidence that Dr. Gabriel's

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[7] 418 Mich. at 21.

[8] 418 Mich. at 21.

[9] 418 Mich. at 24.

[10] 418 Mich. at 24.

[11] The Court of Appeals cited *Anton v. State Farm Mut. Automobile Ins. Co.,* 238 MichApp 673, 607 NW2d 123 (1999) in holding that the *Davis-Frye* test limits admissibility of *novel* scientific evidence. The *Anton* opinion, in turn, cited *People v. McMillan,* 213 MichApp 134, 539 NW2d 553 (1995), and *People v. Haywood,* 209 MichApp 217, 530 NW2d 497 (1995), for the proposition that "the *Davis-Frye* rule limits the admissibility of *novel* scientific evidence by requiring the party offering such evidence to demonstrate that it has gained general acceptance in the scientific community." 238 MichApp at 678. The *McMillan* and *Haywood* opinions, in turn, relied on the cited language in *People v. Young* for similar propositions. It should be noted that the statement in *Anton*, relied on by the Court of Appeals here, was only contained in a general discussion of the *Davis-Frye* test and was in no way central to the court's opinion. Indeed, a close reading of the *Anton* opinion reveals nothing about whether the expert theory in issue, a link between stress and Graves' disease, was novel. The Court's focus, as it should have been, was on whether the theory had achieved general scientific acceptance.

testimony was based on novel scientific evidence. 249 MichApp 534 at 545-546. ACOG respectfully submits that the Court of Appeals' conclusion "proceeds from an unduly narrow reading of the opinions invoking the *Frye* rule." *People v. Salvadore Gonzales,* 415 Mich 615, 623, 329 NW2d 743 (1982).[12]

This Court need look no further than its own long line of cases addressing the reliability of lie detector tests to conclude that novelty of a theory is not a prerequisite for judicial scrutiny. In *People v. Becker,* 300 Mich 562, 2 NW2d 503 (1942), the Court properly ruled that it would be error to admit the results of a lie detector test in the absence of testimony demonstrating a general scientific recognition of such tests. The Court revisited the issue thirteen years later in the very case giving rise to the current test for scientific reliability in Michigan, *People v. Davis,* 343 Mich 348. At that time, the Court had before it a record and evidence which prompted it to affirm its earlier ruling that the same type of lie detector test results, based on the same theories, should not be admitted in evidence. The words of the Court are instructive on the issues in this case:

> The tremendous weight which such tests would carry in the minds of a jury requires us to be *most careful* regarding their admission into evidence and *we should not do so before its accuracy and general scientific acceptance and standardization are clearly shown.*

343 Mich at 372 (emphasis added). Another twenty-two years later, this Court again reviewed the state of the evidence for admissibility of lie detector tests in *People v. Barbara*, 400 Mich 352, and again held that the evidence did not demonstrate general scientific acceptability. By that time, decades after its invention, the theory of the polygraph could hardly be called "novel," yet

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[12] Cited in *People v. Young*, 418 Mich at 20.

the Court strongly reaffirmed the use of the *Davis-Frye* test to (1) determine if the expert theory offered met the requirement of general scientific recognition and (2) conclude that it did not.

Had this Court, in deciding *People v. Barbara,* followed the ruling of the Court of Appeals in the case at bar, it would never have conducted its *Davis-Frye* analysis, would never have determined that lie detector tests still do not enjoy general scientific recognition, would have sustained admission of the polygraph experts' conclusions at trial, and would have left it to the jury to decide if the expert opinions had merit, all because the theory was not "novel," and no one could have honestly claimed that it was. As demonstrated by this Court's own opinions, the theory has been around for more than sixty years. Indeed, should trial courts in Michigan now act as the Court of Appeals suggests in its opinion, no party will be able to challenge the use of polygraph results before such evidence is presented to a jury because no party will ever meet the threshold requirement of demonstrating that the theory is "novel."

Of course, this cannot be the result intended by this Court with its opinion in *People v. Young.* As this Court restated then, the ultimate purpose of the *Davis-Frye* rule "is to prevent the jury from relying on unproven and ultimately unsound scientific methods." 418 Mich at 23, quoting *People v. Salvadore Gonzales,* 415 Mich at 623. A limitation of judicial inquiry to "novel" theories, however unproven or unsound they may be, hardly fulfills that purpose. Such a restriction could well lead to all sorts of discarded, disproven, and disallowed theories being resurrected from the ashes of junk science and presented to juries without preemptive action by a judge.

MRE 702 sets forth the controlling standard in Michigan:

> If the court determines that *recognized* scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an

> expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise.

Recognition under MRE 702 translates to "general scientific acceptance for reliability among impartial and disinterested experts." *People v. Young,* 418 Mich at 21. Clearly, the mere fact that a theory or opinion is not novel does not mean that it is recognized or accepted. Old and well-worn theories can be just as unproven and unrecognized as novel ideas. Indeed, human history is replete with examples of theories that, through time, are proven to be unsound or scientifically invalid, even though they once enjoyed widespread recognition and acceptance (the earth is flat, the sun is the center of the universe). These types of theories are not novel, yet they would hardly be admissible in court as "recognized knowledge."

Finally, given the Michigan legislature's adoption of *Daubert* standards in MCL §600.2955 and the similarity of the Michigan and federal rules, the comments of the U.S. Supreme Court on this issue in the *Daubert* opinion are instructive: "Although the *Frye* decision itself focused exclusively on "novel" scientific techniques, we do not read the requirements of Rule 702 to apply specially or exclusively to unconventional evidence. Of course, well-established propositions are less likely to be challenged than those that are novel, and they are more handily defended." 509 US at 593, 113 SCt at 2796 (footnote 11).

MRE 702 permits admission only of expert opinions based on **recognized** scientific, technical or specialized knowledge. The *Davis-Frye* standard is the means by which the trial court should have determined whether Dr. Gabriel's opinions and theories met the mandate of Rule 702. *People v. Young,* 418 Mich at 24. The opinion of the Court of Appeals that a trial court need not conduct a *Davis-Frye* hearing absent a showing of novelty dangerously narrows the range of expert opinion subject to Rule 702's standards and unfairly prejudices the rights of those who would challenge the admission of unscientific, unsound and unaccepted theories

simply because they are old unscientific, unsound and unaccepted theories. To assure that junk science, whether old or novel, stays out of Michigan's courtrooms, ACOG respectfully urges this Court to reverse the decision of the Court of Appeals, reaffirm the obligation of the trial court to conduct a *Davis-Frye* hearing when there is any legitimate question of an expert's opinions being "recognized," and eliminate the arbitrary requirement of novelty imposed by the lower court's opinion.

V. The Argument Over Pitocin

In closing argument, counsel for Plaintiff made the following statements to the jury (italics added for emphasis):

> And the PDR, which is written every year and updated, *that is overseen by the FDA, the federal government.* Now I do not control the federal government. Antonio Craig doesn't control the federal government or the FDA, and I certainly can't go back to 1980 in my time machine and change what the FDA said about what drugs are okay and what drugs aren't okay.
>
> *But you learned in this case that Pitocin isn't on the market any more. Oxytocin is, but not Pitocin.*

The trial court overruled defense counsel's objection that there was no testimony in the case that Pitocin is not on the market any more. [T 26: 26-27].

The italicized statements by Plaintiff's counsel are simply not true. The PDR, or Physician's Desk Reference, is not overseen by the FDA or any other arm of the federal government. Pitocin is on the market today, as it was in 1980 when Antonio Craig was born and in 1997 when this case was tried. No testimony at trial supported the statements made by Plaintiffs' counsel in closing argument.

The Physicians' Desk Reference, or PDR as it is often called, is not a government publication at all. As each annual volume states clearly in its introduction, the PDR is published

by a private publisher "in cooperation with *participating* manufacturers."[13] Although the publication does provide an exact copy of a particular drug's FDA-approved labeling, it in no way represents itself as including *all* drugs that have been approved by the FDA. It includes only those drugs marketed by manufacturers who have chosen to participate in the publication. The first index in each volume, the Manufacturer's Index, makes this fact clear:

> Listed in this index are all manufacturers participating in PHYSICIAN'S DESK REFERENCE®. It is through their courtesy that PDR® is brought to the medical profession.[14]

Nothing in the publication states that it is approved or overseen by the FDA or any other government agency.

Counsel's argument, at a minimum, suggested to the jury that Pitocin had been withdrawn from the market because it was no longer approved by the government, or that the government had said Pitocin is not "okay." Nothing could be further from the truth. Simply put, Pitocin **is** oxytocin. As the Court of Appeals itself recognized in its opinion, Pitocin is simply one brand name for the generic drug oxytocin.[15] Synthetic oxytocin is one of the most commonly used medications in the United States.[16] In 1995, more than 1.3 million American women were given oxytocin to stimulate labor.[17] Synthetic oxytocin is commercially available in the United States as Pitocin and Syntocinon.[18] They are identical in all respects. The

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[13] Foreword to Physicians' Desk Reference, 57th Edition (2003), p. 2. See also 48th-50th Editions (1994-1996) cited by various counsel and witnesses at trial.

[14] Physicians' Desk Reference, 57th Edition (2003), Section 1, Manufacturers' Index, p. 1. See also 48th-50th Editions (1994-1996).

[15] 249 MichApp at 559.

[16] Williams Obstetrics, 21st Ed., p. 474 (2001).

[17] National Center for Health Statistics, cited in Williams Obstetrics, 21st Edition, p. 474 (2001).

[18] Williams Obstetrics, 21st Ed., p. 323 (2001).

government could hardly require withdrawal of Pitocin while leaving "oxytocin" on the market since Pitocin is oxytocin. This is not an inherently dangerous drug, it has not been withdrawn from the market, and the government has not said that it is not "okay." Allowing a jury to hear argument to the contrary, unsupported by evidence at trial, is a manifest injustice to the physicians and hospital staff who employed that drug in the delivery in issue. Their conduct should be judged on the basis of true facts, not inflammatory falsehoods.

Plaintiffs' counsel argues in his brief that his statement was "entirely accurate" and that his assertion was "an accurate inference from the evidence adduced at trial."[19] In fact, it was not. Counsel suggests in his brief[20] that the following chain of reasoning supports his argument:

> (1) *Assertion #1 which was in evidence*: That the PDR (Physician's Desk Reference) contains information on all FDA approved prescription medicines in the United States of America.
>
> (2) *Assertion #2 which was in evidence*: That Pitocin (trade name) was contained within the 1994 version of the PDR and, although thereafter other brands of Oxytocin (e.g. Syntocinon) are still mentioned, Pitocin is neither contained in the 1995 version of the PDR nor PDRs thereafter.
>
> (3) *Reasonable inference*: That the evidence shows that as of 1995, "Pitocin is not on the market any more. Oxytocin is, not Pitocin."

This chain of reasoning is fatally flawed. Even assuming *arguendo* that the first two assumptions are established by the testimony, the **only** logical inference one could draw from those facts is that Pitocin was not an FDA approved prescription medication after 1994. One cannot leap to the further conclusion that Pitocin "is not on the market any more" without proof of additional facts: a drug cannot be on the market without FDA approval, or a drug must be

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[19] Plaintiff-Appellee's Consolidated Brief in Opposition to Appellant Oakwood Hospital's, et al's Application for Leave to Appeal, p. 63.

[20] Id., p. 64.

withdrawn from the market if it no longer has FDA approval. No such evidence is cited in the record. Further, all of these arguments by counsel overlook a simple but critically important fact: Pitocin **is** oxytocin.

No direct evidence that Pitocin was withdrawn from the market after 1994 was ever introduced at trial. No such evidence could have been truthfully offered because that fact is not true. No evidence was offered which would allow a logical (but incorrect) inference that Pitocin had been taken off the market. Defense counsel properly objected that the argument of counsel was not supported by the evidence. The trial court's failure to sustain that objection allowed the jury deciding this case, in which the use of Pitocin was the critical issue, to have it suggested to them in argument that the defendants had been using a drug that was subsequently withdrawn from the market, presumably due to loss of FDA approval. Such erroneous and patently untrue argument, based on facts not proven, would cause any reasonable person to at least consider the possibility that the drug is inherently dangerous and that it should not have been used by the defendants. This argument was highly prejudicial and can hardly be considered harmless for defendants being tried for alleged misuse of Pitocin.

On the very day that members of this Court read this brief, obstetricians delivering babies in the state of Michigan will be inducing and augmenting labor with Pitocin. This drug is used with laboring women on a daily basis in hospitals throughout Michigan and the United States. The physicians and health care providers who use and administer Pitocin should have confidence that their actions in doing so will be judged in courts of law in accordance with the true facts about the drug, and without the influence of non-evidentiary inflammatory argument that is clearly, factually, and indisputably not true. ACOG respectfully submits that a case of this seriousness and magnitude should be decided on the basis of truth. The truth is that Pitocin has

not been withdrawn from the market. This jury was unfortunately, and improperly, told otherwise.

CONCLUSION

The trial court failed to fulfill its assigned "gatekeeping" role to assure that expert testimony presented to the jury in this case met the standards of recognition required by Michigan's rules of evidence and a long line of decisions of this Court. The trial court allowed unrecognized and unsupported expert testimony to be presented to the jury, and improperly allowed factually inaccurate argument to be made on an issue of central importance to the case. Because of the critical importance of these issues to both patients and health care providers involved in litigation over alleged medical errors, ACOG urges this Court to clarify the gatekeeping requirements for admission of expert testimony in Michigan courts, and to reverse the judgments of the courts below.

Respectfully Submitted,

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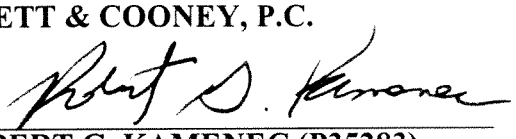
By: 
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STATE OF MICHIGAN
IN THE SUPREME COURT

ANTONIO CRAIG, minor, by his Next Friend and Mother, KIMBERLY CRAIG,

Plaintiff-Appellee,

and

KIMBERLY CRAIG, Individually,

Plaintiff, Not Participating,

v

OAKWOOD HOSPITAL, a Michigan Corporation,

Defendant-Appellant,

and

AJIT KITTUR, M.D., DR. GAVINI, DR. LAKE, MARGARETT LAWRENCE, R.N., J. TYRA, R.N., K. KONIETZKO, R.N., R. HILL, R.N., KAREN SOWISLO, DIRECTOR OF MEDICAL RECORDS, CHILDREN'S HOSPITAL, DR. R. ASMAR, DR. CASH, DR. HERMAN GRAY, DR. H. WALKER, DR. MARY LOGAN, DR. CAROLYN JOHNSON,

Defendants, Not Participating,

and

ASSOCIATED PHYSICIANS, P.C. and ELIAS G. GENNAOUI, M.D., and HENRY FORD HOSPITAL d/b/a HENRY FORD HEALTH SYSTEM,

Defendants.

/

Supreme Court No. 121419

Court of Appeals No. 206951

Wayne County Circuit Court No. 94-410338-NH

PROOF OF SERVICE

STATE OF MICHIGAN)
) ss.
COUNTY OF OAKLAND)

Audra Arndt, being first duly sworn, deposes and says that he is a shareholder with the firm PLUNKETT & COONEY, P.C., and that on the 17th day of November, 2003, she caused to be served two copies of the Brief of Amicus Curiae The American College of Obstetricians and Gynecologists ("ACOG") and Proof of Service upon the following:

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